

Applicant: Kurt-Reiner Geiss
Application No.: 10/665,394
Examiner: Snigdha Maewall

Remarks

Claims 14 and 23 have been amended. Claims 16 and 20-22 have been cancelled. Claims 1-13 were cancelled in the previous Response of December 19, 2008. New claims 37-46 have been added. Claims 14, 15, 17-19, and 23-46 are presented for the Examiner's review and consideration. Applicant believes the claim amendments and the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Interview

Applicant thanks the Examiner and her supervisor, Kishore Gollamudi, for courtesies extended to Applicant's representatives, Paul Bianco and Katharine Davis Wong, and Assignee's representatives, Ralf Jaegar and Martin Purpura, during the telephone interview of May 6, 2009. The experimental results presented in the previous Declaration filed on December 19, 2008 were discussed. The new Declaration, amendments, remarks, and Exhibits A-F presented herein reflect the discussion of the interview.

Amendments to the Claims

No new matter has been added by the amendments to claims 14 and 23 made herein. These claims have been amended to clarify the amounts of phosphatidyl serine and carbohydrates included in the composition of the food/food bar; *i.e.* 100mg to about 200mg of phosphatidyl serine and 10g to about 20g of carbohydrates. These amounts correspond with the amounts used in the experimental examples presented in both the previously and currently-filed Declarations. Additionally, this amount of phosphatidyl serine is within the range disclosed in the specification, 100mg to 300mg. The amount of carbohydrates is disclosed in the specification as "relatively high", particularly 15g or 20g per 35g. *See abstract; paragraph [0020]; and Figure 2A of the published application, U.S. Patent Application Publication 2004/0120985 A1;*

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hereinafter “published application.”

No new matter has been added by the addition of claims 37-39. These claims were added to indicate that the carbohydrates included in the food/food bar have a high glycemic index (GI) such that the glucose intake in the consumer of the food/food bar can markedly increase upon consumption of the food/food bar. *See paragraph [0020] of the published application.*

No new matter has been added by the addition of claims 40-42 and 46. These claims clarify that the phosphatidyl serine and carbohydrates have a greater effect on cognitive functional capacity when consumed together in the food/food bar than the effect each has when consumed separately. The results of the experiments presented in both the previously and currently-filed Declarations demonstrate this concept. Additionally, the combination effect is mentioned in the specification as originally filed. *See paragraphs [0019]-[0022] and [0054] of the published application.*

No new matter has been added by the addition of claims 43-45. The subject matter of these new claims is supported by cancelled claims 20-22. New claim 43 is claim 20 rewritten in an independent format and new claims 44 and 45 correspond to dependent claims 21 and 22.

Objection to the Claims

Claim 23 was objected to under 37 C.F.R. 1.75(c) as being of improper dependent form for allegedly failing to limit the subject matter of a previous claim. Specifically, the Examiner asserts that claim 23 recites a limitation of combination including a minimum of 100mg to about 300mg of phosphatidyl serine which does not further limit the amount claimed in claim 16 as an amount of 200-300mg.

In response, Applicant respectfully submits that claim 23 is an independent claim and was presented as such in the previous Response filed on December 19, 2008.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of this objection to the claims.

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Rejection under 35 U.S.C. §103(a)

Claims 14-36 were rejected under 35 U.S.C. §103(a), as being unpatentable over Buchholz et al. (U.S. Patent 6,514,973 B1; hereinafter “Buchholz”) in view of Lang et al. (U.S. Patent Application Publication 2003/0161861 A1; hereinafter “Lang”). Claims 16 and 20-22 have been cancelled. New claims 43-45 correspond to the cancelled claims 20-22. For reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

It is noted that the references are described individually only to clarify what each reference teaches and not to argue each reference separately. The teachings of Buchholz and Lang are as applied in the previous Response filed on December 19, 2008 and are reiterated herein for the convenience of the Examiner.

Buchholz

Buchholz discloses compositions for the treatment and prevention of transmethylation disorders, particularly for the treatment of neurological and pathopsychological diseases. *See* column 1, lines 6-8. The compositions contain three active ingredients; component A: one or more phosphatidyl serines, component B: one or more methyl transporters, and component C: one or more compounds selected from methyl and methylene donors, provided that the phosphatidyl serines and compounds with methyl transporting properties do not form part of component C. *See* abstract and column 1, line 61 to column 2, line 7. These compositions are useful for reducing elevated levels of homocysteine found in transmethylation disorders. *See* column 1, line 37 to column 2, line 12.

Buchholz discloses, as background, a previous study demonstrating the long-term benefits of phosphatidyl serine supplementation. In this study, it was documented that oral supplementation with 200-300mg of phosphatidyl serine per day for 2 to 6 months improves brain metabolism and benefits cognitive functions such as memory, thinking, learning, and the ability to concentrate, especially in aging people and in patients with certain neurological and pathopsychological conditions. *See* column 2, lines 22-27. However, in the actual composition

disclosed by Buchholz, phosphatidyl serine was added only in an amount of 50mg. *See Example 1.*

Buchholz does not teach the role of carbohydrates in improving cognitive function of the brain. Further, Buchholz does not discuss any connection or relationship between phosphatidyl serine and glucose intake in the brain, other than to mention that it has been assumed that phosphatidyl serine is able to stimulate glucose metabolism in the brain. *See column 2, lines 32-37.*

The compositions disclosed by Buchholz are suitable as a food or food supplement and are prepared by combining the active ingredients, components A-C, with edible “nutritional substances”, including carbohydrates. Thus, Buchholz adds carbohydrates only to make the phosphatidyl serine more palatable for consumption, and therefore, considers the “nutritional substances”, such as carbohydrates, inactive ingredients. *See column 5, lines 40-49 and column 6, lines 9-12.*

Lang

Lang discloses the use of a cereal product such as a biscuit or cracker having a slowly digestible starch content relative to the total starch content higher than about 12 wt %, preferably higher than about 20 wt %, to improve cognitive performances, in particular memory retention, attention, concentration, vigilance and/or mental well-being in people, and particularly in a child and an adolescent. *See abstract.*

In the background material, Lang discusses conflicting experimental results regarding the role of glucose in cognitive functions, some studies show glucose improves these functions, and others show glucose has no role in these processes. *See paragraphs [0015] and [0016].* In actual results, Lang shows that the regulation of the glycemic index alone was insufficient to increase cognitive performances and demonstrates that certain cereal products significantly improve cognitive performance, by virtue of the choice of appropriate proportions between slowly

digestible starch and the total starch present in the product. *See paragraph [0017].* Lang does not disclose or suggest the use of phosphatidyl serine in the biscuit composition.

In experimental Example 1, Lang compares learning and locomotive activity in two groups of rats, one of which consumes Lang's biscuits and the other ready-to-eat cereals. The rats which consumed biscuits exhibited learning results which were significantly superior to those of the rats which consumed ready-to-eat cereals. Additionally, in locomotive activity, the rats which consumed a biscuit-based breakfast were calm, whereas the rats which consumed a breakfast based on ready-to-eat cereals were more active and showed signs of distress (more passages in the central compartment, this indicating higher distress, since the behavior of crossing a room along the diagonal rather than along the walls is unusual in rats). Lang concludes that the bioavailability of starch makes it possible to explain the differences in results in these experiments. As such, Lang discloses improving cognitive performance by consuming a food product which combines a certain proportion of slowly digestible starch with respect to the total starch content.

Instant Invention

Generally, the present invention provides a food/food bar for increasing/improving cognitive functional capacity, particularly a food for increasing memory, concentration, and attentiveness in the consumer of the food. *See abstract and paragraph [0012] of the published application, and claims 3 and 12 as originally filed.* This food, preferably a bar of chocolate, has a phosphatidyl serine content ranging from 100-300mg and a relatively high carbohydrate content. *See abstract.* A preferred food/food bar, as currently claimed, includes a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of carbohydrates. *See abstract; paragraph [0020]; and Figure 2A of the published application.* In one embodiment, the food/food bar contains a minimum of 40 wt% to about 57 wt% of carbohydrates and a minimum of 1 wt% to 1.4 wt% of lecithin extract containing phosphatidyl serine. *See paragraph [0022] of the published application.*

This food/food bar has a relatively high content of simple carbohydrates, such as glucose, fructose, sucrose, and/or combinations thereof. By specifically combining the intake of carbohydrates and phosphatidyl serine, the glucose intake, and thus the glucose content in the brain cells, is markedly increased. In the short term, this makes possible an especially marked increase in the cognitive functional capacity. Furthermore, when consumed regularly, three to four bars per week suffice to sustain a long-term increase of cognitive functional capacity. *See* paragraphs [0025] and [0053] of the published application.

Additionally, the invention provides methods for improving cognitive functional capacity in consumers of the claimed food product/bar. *See* claim 3 as originally filed.

Argument

Applicant respectfully submits that the combination of Buchholz and Lang does not obviate the invention as currently claimed. Independent claims 14, 23, and 32 recite, *inter alia*, a food/food bar for improving cognitive functional capacity of a consumer of the food/food bar. The food/food bar includes a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of carbohydrates. Upon consumption of the food/food bar glucose intake into the brain cells of the consumer is improved. Additionally, independent claim 43 recites, *inter alia*, a method for improving the cognitive functional capacity by consuming the food/food bar.

The Examiner asserts that although Buchholz does not explicitly teach the role of carbohydrates in improving cognitive function of the brain, Lang remedies this deficiency by disclosing a starch-containing cereal product that improves cognitive performance. Thus, the Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time that the invention was made to incorporate carbohydrates into the composition of Buchholz, since Lang teaches that carbohydrates improve cognitive function.

Applicant respectfully disagrees. Based upon both the written Office Actions and the discussions in the interviews with the Examiner and her supervisor, Applicant respectfully

submits that the Examiner appears to believe that the instant invention is predictable from/suggested by the combination of the teachings of Buchholz and Lang simply because Buchholz discloses a composition including phosphatidyl serine and Lang discloses a composition including starch. The fact that one element, *i.e.* phosphatidyl serine, of an invention is disclosed in one reference (Buchholz) and another element, *i.e.* starch, is disclosed in a second reference (Lang) does not, in and of itself, render the claimed invention an obvious combination of the two references.

“The question under 35 USC 103 is not merely what the references expressly teach but what they would have suggested to one of ordinary skill in the art at the time the invention was made.” In re Lamberti, 545 F.2d at 750, 192 USPQ at 280 CCPA 1976.

As noted above, the claimed invention is a food/food bar, including a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of carbohydrates, for improving cognitive functional capacity. This food/food bar is not suggested by the combined teachings of Buchholz and Lang nor is there any reasonable basis for suggestion or motivation to combine the teachings in the first place.

The Examiner asserts that the motivation to add the starch of Lang to the composition of Buchholz in order to prepare the claimed food/food bar lies in two facts, the first disclosed by Buchholz and the second by Lang; *i.e.* Buchholz teaches that phosphatidyl serine both stimulates glucose metabolism in the brain and increases the number of neurotransmitter receptor sites and Lang teaches that starch improves cognitive performance.

First, Applicant points out that the claims do not recite “stimulation of glucose metabolism in the brain” or “increasing the number of neurotransmitter receptor sites in the brain.” Thus, these facts are not relevant to the claims as currently pending and knowledge of them would not get one any closer to obtaining the claimed food/food bar.

As indicated by the above teachings (of Buchholz and Lang), it is clear that Buchholz and Lang do not disclose analogous compositions. These compositions (of Buchholz and Lang) are

unrelated to each other and to the invention. Furthermore, any combination of Buchholz and Lang would not result with the food/food bar as currently claimed.

Buchholz discloses a food composition including phosphatidyl serine as an “active” ingredient and various types of carbohydrates as “nutritional substances.” Buchholz does not suggest that glucose, or any other carbohydrate, would have an effect on the function of his composition, or would interact with phosphatidyl serine in the composition to improve cognitive function. This is clearly evident from his designation of carbohydrates as “nutritional substances” rather than “active ingredients.”

Lang does not disclose that foods merely containing “starch” or “carbohydrates” are capable of improving cognitive function, but rather discloses a cereal product, having a specific ratio of slowly-digestible starch to total starch content, which is capable of improving cognitive function. It is the choice of the appropriate ratio that produces the positive effects on cognitive function. This is clearly evident in the experimental examples of Lang wherein he tested his food product against ready-to-eat cereals that also contained carbohydrates, but did not improve cognitive functions.

Even in the rare instance that one would combine the disclosures of Buchholz and Lang, in light of the above, why would one of ordinary skill in the art be motivated to incorporate any part of Lang’s composition into Buchholz’s composition? Where is the suggestion that the addition of a specific ratio of slowly-digestible starch to total starch to the food product of Buchholz improves or enhances Buchholz’s food product? At the time of the invention, would one think that slowly-digestible starches can improve or enhance the function of phosphatidyl serine? Without answers to these questions, one of ordinary skill in the art would have no reason or motivation to combine the teachings of Buchholz and Lang.

In responding to Applicant’s previous arguments, the Examiner draws several conclusions from Applicant’s statements regarding the teachings of Lang.

First “*Applicant argues that Lang discloses that some studies improve cognitive performance whereas some do not. This argument is not considered persuasive because the*

reference's teachings are taken as a whole and because the reference teaches some carbohydrates do not increase cognitive performance, does not negate the fact that carbohydrates do increase cognitive performance."

Specifically, in the previous Response, Applicant noted that Lang discloses conflicting results regarding levels of glucose and improvement of cognitive functions. *See paragraphs [0015] and [0016]* of Lang. Applicant respectfully submits that the Examiner has misinterpreted the point of this statement as she appears to be focusing only on what the references explicitly teach and not on the other requirements of 35 USC 103(a). This statement was not made in an attempt to negate the fact that some carbohydrates increase cognitive performance or to separate the teachings of Lang from the whole. Rather, it was made to show that data available in the prior art is not definitive as to how carbohydrates effect cognitive performances and thus, such effects are not easily predictable.

Additionally, at the time of the invention, less than definitive data on the influence of phosphatidyl serine on cognitive function and memory was also present in the prior art. For example, results from an experiment disclosed by Jorissen et al. (*Nutrition Neuroscience* 4(2):121-134 2001; abstract attached hereto as "Exhibit A") concludes that a daily supplement of phosphatidyl serine (300mg or 600mg for 12 weeks) does not affect memory or other cognitive functions in older individuals with memory complaints. Conversely, Schreiber et al. (*Israeli Journal of Psychiatry and Related Science* 37(4):302-307 2000; abstract attached hereto as "Exhibit B") demonstrates improvement in patients having age-related cognitive decline after supplementation with 300mg phosphatidylserine for twelve weeks.

Applicant points out that this non-conclusive information regarding the affects of both phosphatidyl serine and carbohydrates on cognitive functions sheds doubt on the alleged predictability of the claimed invention.

Further, the Examiner states, "*Applicant argues that Lang does not teach phosphatidyl serine. In response to this argument, the Examiner respectfully states that Lang was not cited for phosphatidyl serine, Buchholz was cited for phosphatidyl serine. In response to Applicant's*

argument against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.”

Again, the Examiner has misinterpreted the point of the argument. First, the Examiner’s attention is drawn to the statement above at page 9 and also at page 8 of the previous Response: “*It is noted that the references are described individually only to clarify what each reference teaches and not to argue each reference separately.*” Applicant agrees that the rejection is based on a combination of Buchholz and Lang. However, since it is a combination, Applicant can point out what elements of the claimed invention are not taught by each reference, regardless of what each reference is cited to teach, in order to further refute reasonable combination of the references.

The claimed food/food bar provides measurable improvements in cognitive functional capacity upon consumption that can not be predicted from the teachings of Buchholz and Lang. The effect of the combination of phosphatidyl serine and carbohydrates on concentration, memory, and attention is demonstrated in the first experimental example provided in both the attached Declaration and previously-submitted Declaration of the inventor, Dr. Kurt-Reiner Geiss. In this experiment, improvements in concentration, memory, and attention were observed in the subjects after twelve weeks of consuming the bars and the improvements declined after the subjects stopped consuming the bars.

The study volunteers were evaluated pre-supplementation and after twelve weeks of consuming one IQPLUS Brain Bar per day for the first two weeks, followed by half an IQPLUS Brain Bar for the next ten weeks. The IQPLUS Brain Bar contains 200mg of phosphatidyl serine and 20g of carbohydrates. After the second evaluation, the volunteers stopped consuming the IQPLUS Brain Bars and were re-evaluated during week twenty-four. The combination of phosphatidyl serine and carbohydrates in the form of the IQPLUS Brain Bar resulted in improvements in all categories of concentration, attention, and memory tested (results after twelve weeks of IQPLUS Brain Bar consumption in comparison to starting values). A comparison of results after twelve weeks consumption with results after an additional twelve

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weeks without any further supplementation showed a decline in all categories at week twenty-four. The results regarding concentration and attention are shown in Table 2 and results regarding memory and attention are shown in Table 3 (Declaration, experimental example one).

With regard to this experiment, the Examiner concludes that the data presented is not commensurate in scope with the claims and states "*The declaration contains only 200mg of phosphatidyl serine and 20g of carbohydrates whereas the claims as recited require the limitation of a minimum of 100mg of phosphatidyl serine and a minimum of 15g carbohydrates, as such no data has been provided for amounts which are below 200mg of phosphatidyl serine and less than 20g of carbohydrates.*"

Applicant respectfully disagrees. The claims, as currently pending, recite minimums of about 100mg to 200mg phosphatidyl serine and about 10g to 20g carbohydrates. The subjects participating in the IQPLUS Brain Bar study (experimental example 1, described above) consumed one bar, one bar including 200mg phosphatidyl serine and 20g of carbohydrates, per day for the first two weeks of the study. The subjects then consumed a half of a bar for the following twelve weeks. One half of a bar contains 100mg of phosphatidyl serine and 10g of carbohydrates. Accordingly, the average consumption per subject was 117mg of phosphatidyl serine and 11.7g of carbohydrates for the duration of the twelve week study. Thus, the range of amounts of phosphatidyl serine and carbohydrates exemplified in the experimental examples is commensurate with the range of amounts claimed.

As noted above, based upon discussions with the Examiner and her supervisor, the Examiner appears to believe that any reference describing food products containing carbohydrates can be used in concert with Buchholz to obviate the claimed invention. Applicant respectfully submits that this approach is insufficient to reasonably support the rejection of the claims.

All types of carbohydrates are not equivalent nor are they metabolized in the same manner upon consumption; *i.e.* each type produces different fluctuations in blood glucose levels. This fluctuation is measured by the glycemic index (GI). Many people who are weight-conscious

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and/or suffer from diabetes benefit from a diet consisting of food having a low glycemic index. Thus, considering the numbers of people suffering from this condition(s), even a quick internet search provides much information regarding the differences among carbohydrate foods. *See*, for example, attached Exhibit C, accessed from the Official website of the Glycemic Index and GI Database, which lists the glycemic index of many foods and provides advice for people switching to a low GI diet. Many simple carbohydrates have a high glycemic index and are quickly digested. Conversely, some starches have lower glycemic indexes and are slowly digested. Thus, in contrast to the Examiner's assertion, all carbohydrates can not be used interchangeably to provide the same effects upon consumption. Therefore, the starch of Lang is not an obvious substitute for the simple carbohydrate of the claimed food/food bar.

A plethora of bars and drinks high in carbohydrate content and/or glycemic index are known in the art and are consumed to provide quick energy. Likewise, phosphatidyl serine supplements are known in the art and are consumed to provide improvements in cognitive functions. Carbohydrates have been added to phosphatidyl serine supplements to make them more palatable for consumption. However, no one has added carbohydrates to phosphatidyl serine supplements with the purpose or expectation that the carbohydrates would be an "active" ingredient and would interact with the phosphatidyl serine to actively improve cognitive functions, such as memory, concentration, learning, and attentiveness. The instant inventor has discovered this unexpected functional relationship between phosphatidyl serine and simple carbohydrates. Such an unexpected functional relationship demonstrates that the claimed food/food bars are not obvious in view of the cited patent documents (Buchholz and Lang) or any other prior art.

Evidence of a greater than expected result may be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately (*i.e.* demonstrating "synergism"). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). MPEP 716.02(a).

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The term “synergism” is commonly defined as the interaction of elements that when combined produce a total effect that is greater than the sum of the individual elements. *See* definition of “synergism” as accessed from the web site www.dictionary.com and attached hereto as “Exhibit D”.

The phosphatidyl serine and the carbohydrates combined in the claimed food/food bar interact synergistically to provide measurable improvements in cognitive functional capacity upon consumption. Applicant demonstrated a greater than expected increase in cognitive functional capacity after consumption of a combination of phosphatidyl serine and simple carbohydrates over consumption of phosphatidyl serine or simple carbohydrates alone (shown in the second experimental example provided in both the attached Declaration and previously-filed Declaration of Dr. Kurt-Reiner Geiss). In this experiment, the influence of the claimed food bar on cognition during golfing (tee-off accuracy) was tested and compared to the influence of the ingredients (phosphatidyl serine and simple carbohydrates) alone.

The term “cognition” is commonly defined as the act or process of knowing, which includes perceiving, recognizing, conceiving, judging, reasoning, and imagining. *See* definition of “cognition” as accessed from the web site www.dictionary.com and attached hereto as “Exhibit E”. Thus, it can be said that cognition refers to the processing of information and applying the information processed. The performance of a “golf swing” requires a certain level of cognition. The golf swing is a complex motion and, especially at tee-off, creates high levels of tension with potential negative effects on cognitive function, including memory, attentiveness, and concentration. Memory and focus (attentiveness) play a major role during the golf swing as the golfer has to memorize the perfect swing and recall the motion while trying to hit the ball to the best of his/her ability and all the while staying focused to avoid mistakes. Thus, cognition, memory, focus, and attentiveness are linked with regard to performing a golf swing. Golfers participating in the clinical study first performed a standardized ten minute warm-up that did not include practice shots. After the warm-up, the golfers teed-off twenty times in fifteen second intervals and were asked to hit a target at a distance of 135 meters. The quality of the ball flight

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was recorded immediately after the ball hit the ground after tee-off. A good ball flight (hit) was defined as “correct flight”, “draw”, or “fade”, whereas all other ball flights were recorded as a miss. A schematic representation of ball flight is shown in Figure 2 of example two. After the first test, the golfers consumed a combination of 200mg phosphatidyl serine and 20g of simple carbohydrates (as IQPLUS Golf Bar, n=10), 20g of simple carbohydrates (as a nutrition bar, n=10), or 200mg of phosphatidyl serine (as soft gel capsules, n=2) for six weeks. After six weeks, the ball flight test was repeated. It was found that the combination of phosphatidyl serine and simple carbohydrates resulted in a significant improvement of good ball flights, whereas simple carbohydrate or phosphatidyl serine consumption did not improve performance. *See* “results” section of experimental example two for pre-test and post-test statistical comparisons. Thus, per definition, these results show a synergistic effect. The improvements are known to be due to mental aspects, in light of the conditions of the experiment, *i.e.* the physical, mental, and golf-specific training habits of each individual participant remained unchanged during the supplementation phase.

The Examiner does not find any synergism in Applicant’s examples and asserts that a review of Figure 3 (at page 7 of the previously-filed Declaration) does not show any difference between pre and post carbohydrate levels.

Applicants respectfully disagree. The Carbohydrate group showed an improvement of 1.3% (post 7.9, pre 7.8; difference 0.1=1.3% improvement) in comparison to an improvement of 21.7% for the PS and Carbohydrate Group (post 10.1, pre 8.3; difference 1.8=21.7% improvement). *See* section entitled “result” at the bottom of page 6 of the previously-filed Declaration. Thus, in contrast to the Examiner’s assertion, the data shows a difference in performance between pre and post carbohydrate levels.

The synergistic effect is apparent from even a quick comparison of the dark bars (post supplementation) of Figure 3 (at page 7 of the previously-filed Declaration) shows that the golfers who consumed the food bar (phosphatidyl serine and carbohydrates) achieved a greater amount of correct ball flights than did the golfers who consumed carbohydrates alone or

phosphatidyl serine alone combined. This combination of phosphatidyl serine and simple carbohydrates resulted in a statistically significant ($p < 0.05$) improvement of good ball flights, which can result with improved golf scores overall. *See* section entitled “Results” at pages 6-7 of the currently-filed Declaration). Furthermore, regarding the data of Figure 3, if one achieves only a small increase with phosphatidyl serine or carbohydrates, one would not expect the combination to provide greater and/or better results.

Additionally, Applicant conducted a further experiment with golfers using identical conditions as the above-described experiment (Experimental Example Two). The subjects (n=2) consumed 150mg of phosphatidyl serine and 15g of carbohydrates on average per day for a period of eight weeks. This group showed a 14% improvement in good ball flights (pre 6.5; post 7.4; difference 0.9 = 14%). *See* “Experimental Example Three” of the currently-filed Declaration).

The Examiner indicated some concerns with the dietary restrictions placed on the subjects in the experiments. *Applicant has not provided the data with respect to various other foods that the person under examination has consumed. What food in addition to the bar was consumed by the subject population? Did they consume no carbohydrate or did they consume eggs which contain phosphatidyl serine?*

In all studies, subjects were instructed to avoid changes in their diet and in their physical, mental, and golf-specific training during the study. This is generally an art-accepted way to exclude interference from nutrients coming from the daily diets of the subjects. *See* item 12 at page 7 of the currently-filed Declaration. However, regardless of dietary restrictions, it is known that phosphatidyl serines are not abundant in common foods. *See* Buchholz, column 2, lines 38-40. For example, eggs and poultry are not good sources of phosphatidyl serine, since they do not contain measurable and hence meaningful amounts (of phosphatidyl serine). *See* Table III of Weinrauch et al. (Journal of the American Oil Chemists’ Society 60(12): 1971-1978, December 1983; article attached hereto as “Exhibit F”).

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The Examiner asserts that the claims do not recite the synergistic effect of phosphatidyl serine and carbohydrates and concludes that the scope of the claims is not commensurate with the Declaration.

In response, Applicants point out that claims 40-42 and 46, as presented herein, encompass the synergistic effect of phosphatidyl serine and carbohydrates.

Accordingly, based upon the three above-described experiments, in contrast to the Examiner's conclusions, it is clear that Applicant has provided evidence of a synergistic effect on cognitive functional capacity from the combination of phosphatidyl serine and simple carbohydrates over the effect of each ingredient alone (*i.e.* phosphatidyl serine alone and simple carbohydrates alone).

Furthermore, as established above, one of ordinary skill in the art would not consider the compositions of Buchholz and Lang as analogous or related in any way. One would not have any reason or motivation for incorporating the carbohydrates of Lang into the composition of Buchholz because neither Lang nor other prior art suggests that specific ratios of slowly-digestible starch to total starch combined with phosphatidyl serine would improve/increase the ability of Buchholz's composition to treat transmethylation disorders. Regardless, the incorporation would not result with the food/food bar as currently claimed.

Neither the cited patent documents (Buchholz and Lang) nor any other prior art teach or suggest a food/food bar (or methods for using the food/food bar), including a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of carbohydrates, for improving the cognitive functional capacity of a consumer of the food/food bar. Thus, even if one of ordinary skill in the art were to combine the teachings of Buchholz and Lang, the food/food bar, as currently claimed, would not be the result. Additionally, neither the cited patent documents nor other prior art teach the unexpected beneficial results (synergistic effect) of the combination of at least a minimum of 100mg to about 200mg of phosphatidyl serine and a minimum of 10g to about 20g of carbohydrates, particularly simple carbohydrates having a high glycemic index.

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Accordingly, Applicant respectfully submits that independent claims 14, 23, 32, and 43 are patentable over Buchholz in view of Lang. As claims 15, 17-19, 37, and 40 depend from claim 14; claims 24-31, 36, 38, and 41 depend from claim 23; claims 33-35, 39, and 42 depend from claim 32; and claims 44-46 depend from claim 43, these dependent claims necessarily include all the elements of their base claims. Thus, Applicant respectfully submits that the dependent claims are allowable over Buchholz in view of Lang at least for the same reasons.

In light of the foregoing arguments, Exhibits A-F, and both the previously-filed and attached Declarations under 37 C.F.R § 1.132, Applicant requests reconsideration and withdrawal of this rejection under 35 U.S.C. §103(a).

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Conclusion

In light of the foregoing amendments, remarks, Exhibits A-F, and both the previously-filed and attached Declarations under 37 C.F.R. § 1.132 this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned. The fee for an extra independent claim pursuant to 1.16(h) in the amount of \$220 and the fee for six extra dependent claims pursuant to 1.16(i) in the amount of \$312 are believed to be due and are being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7390-X03-018).

Respectfully submitted,

/Katharine F. Davis Wong/

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